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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

*Friedman et al.*

Appl. No.: 10/780,295

Filed: February 17, 2004

For: Modulators of Body Weight,  
Corresponding Nucleic Acids and  
Proteins, and Diagnostic and  
Therapeutic Uses Thereof

Confirmation No.: 7125

Art Unit: 1647

Examiner: Saoud, Christine J.

Atty. Docket: 16454.0002 D2

### Mail Stop Petition

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450


### REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. §1.705(b)

In response to the Decision holding Applicant's previous request for reconsideration of Patent Term Adjustment in abeyance mailed March 16, 2009 (copy attached), Applicant resubmits a written request for reconsideration of the patent term adjustment for Office failure to issue the patent within 3 years. Applicant respectfully requests reconsideration of the Patent Term Adjustment indicated on page 3 of Form PTOL-85 (i.e., Determination of Patent Term Adjustment under 35 U.S.C. 154(b)), which Form PTOL-85 was mailed October 8, 2008. Applicant herein applies for an adjustment of the patent term due to, at least, to a delay on the part of the Patent Office in issuance of the patent. Applicant further submits for consideration, a statement of the facts involved as required under 37 CFR 1.705(b)(2).

The Commissioner has already charged Applicant's Deposit Account 19-4293 for the petition fee as set forth in 37 CFR 1.18(e). Applicant does not believe any fees are due. However, should this be in error, the Commissioner is hereby authorized to debit or credit Deposit Account 19-4293.

Respectfully submitted,

Date: 5-7-09  
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Harold H. Fox  
Reg. No. 41,498

05/08/2009 SMOHAMM1 00000033 194293 10780295  
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Re: Reconsideration of Patent Term Adjustment  
U.S. Patent No. 7,521,258  
Atty. Docket: 16454.0002 D2  
Page 1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:

*Friedman et al.*

U.S. Patent No.: 7,521,258

Issued: April 21, 2009

For: Modulators of Body Weight,  
Corresponding Nucleic Acids and  
Proteins, and Diagnostic and  
Therapeutic Uses Thereof

Confirmation No.: 7125

Art Unit: 1647

Examiner: Saoud, Christine J.

Appl. No.: 10/780,295

Filed: February 17, 2004

**Statement of Facts in Support of Application for Reconsideration of Patent Term Adjustment  
Pursuant to 37 C.F.R. § 1.705(b)**

**Mail Stop – Patent Ext.**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Statement of Facts is being submitted pursuant to in support of an Application for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(b).

The Patent Term Adjustment (PTA) that is indicated on page 3 of Form PTOL-85 (i.e., Determination of Patent Term Adjustment under 35 U.S.C. 154(b)) is 330 days. Applicant submits that the correct PTA is 586 days, in view of 37 C.F.R. §§ 1.703– 1.705 and as clarified in the recent decision in *Wyeth v. Dudas*, No. 07-1492 (D.D.C. 2008). Relevant instances, and associated dates and impact of such instances to the correct PTA to which the above-identified patent is entitled, follow.

Relevant instances, and associated dates and accorded PTA

The PTA calculation for this application begins with the actual date that the above-identified application was filed under 35 U.S.C. 1.111(a) and the requirements of C.F.R. § 1.53(b) satisfied, which is February 17, 2004. Review of all instances that have occurred subsequent to the actual filing date and up to the mailing of the Notice of Allowability for the above-identified application that may impact PTA reveals that there are three instances under 37 C.F.R. § 1.702 and 37 C.F.R. § 1.703 that properly increase PTA and three instances under 37 C.F.R. § 1.704 that reduce PTA for the above-identified patent. The relevant dates of these instances, and PTA accorded these instances, are provided below and further outlined in EXHIBIT A, attached hereto.

1. On June 26, 2006, the Patent office mailed a first non-final Office Action (i.e., a Requirement for Restriction/Election). Under 37 C.F.R. § 1.703(a)(1), the Office's delay in mailing the non-final Office Action increases PTA by 435 days.

2. On September 29, 2006, Applicant mailed a Response to the non-final Office Action referenced in Item 1. Under 37 C.F.R. § 1.704(b), Applicant's delay in responding to the non-final Office Action reduces PTA by 3 days.

3. On July 5, 2007, Applicant mailed a Response to non-final Office Action, which non-final Office Action was mailed on January 10, 2007. Under 37 C.F.R. § 1.704(b), Applicant's delay in responding to the non-final Office Action reduces PTA by 86 days.

4. On October 30, 2007, Applicant filed a Request for Continued Examination in response to a final Office Action, which final Office Action was mailed on September 19, 2007. Under 37 C.F.R. § 1.703(b)(1) and in view of the recent decision in *Wyeth v. Dudas*, No. 07-1492 (D.D.C. 2008), the Office's delay in issuing a patent from the subject application within three years of the actual filing date of the subject application, less the number of days beginning from the date of the filing of the RCE and ending on the date on which the patent will ultimately issue, increases PTA by 256 days.

5. On July 2, 2008, Applicant mailed a Response to non-final Office Action, which non-final Office Action was mailed on February 4, 2008. Under 37 C.F.R. § 1.704(b), Applicant's delay in responding to the non-final Office Action reduces PTA by 22 days.

6. On October 10, 2008, the Patent Office mailed a Notice of Allowance in response to Applicant's Response listed in Item 5, above, which Response was mailed on July 2, 2008. Under 37 C.F.R. § 1.703(a)(2), the Office's delay in mailing the Notice of Allowance increases PTA by 6 days.

Applicant states that the above-identified patent is not subject to a terminal disclaimer.

### CONCLUSION

By way of the foregoing comments, attached EXHIBIT A, and the Application submitted herewith, Applicant asserts that the provisions of C.F.R. § 1.705(d) have been satisfied. Accordingly, Applicant respectfully requests reconsideration of PTA calculated by the Patent Office, and correction of the PTA such that the full term adjustment to which the patent is entitled, 586 days, is accorded indicated on the face of the above-identified patent.

No additional fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Deposit Account 19-4293 referencing Docket No. 16454.0002 D2. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Deposit Account 19-4293.

Respectfully submitted,

Date: 5-7-09  
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Washington, DC 20036  
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Fax: 202-429-3902


  
Harold H. Fox  
Reg. No. 41,498

EXHIBIT A

| Relevant Date         | Relevant Instance                              | Dates for PTA calculation<br>&<br>C.F.R. provision                                    | Days added or<br>subtracted for<br>PTA                                |
|-----------------------|------------------------------------------------|---------------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| February 17,<br>2004  | Subject application<br>filed.                  | Not applicable.                                                                       | Not applicable.                                                       |
| June 26, 2006         | Restriction<br>Requirement mailed.             | February 17, 2004, through<br>June 26, 2006.<br><br>§§1.702(a)(1) and<br>1.703(a)(1). | 435 days charged<br>to PTO and<br><b>added</b> to PTA.                |
| September 29,<br>2006 | Response to non-Final<br>Office Action mailed. | June 26, 2006, through<br>September 29, 2006.<br><br>§1.704(b).                       | 3 days charged to<br>Applicant and<br><b>subtracted</b> from<br>PTA.  |
| July 5, 2007          | Response to non-Final<br>Office Action mailed. | January 10, 2007, through<br>July 5, 2007.<br><br>§1.704(b).                          | 86 days charged<br>to Applicant and<br><b>subtracted</b> from<br>PTA. |
| October 30,<br>2007   | Examination                                    | February 17, 2007, through<br>October 30, 2007<br><br>§1.703(b)(1).                   | 256 days charged<br>to PTO and<br><b>added</b> to PTA.                |
| June 2, 2008          | Response to non-Final<br>Office Action mailed. | February 11, 2008, through<br>June 2, 2008.<br><br>§1.704(b).                         | 22 days charged<br>to Applicant and<br><b>subtracted</b> from<br>PTA. |
| October 8,<br>2008    | Notice of Allowance<br>mailed.                 | June 2, 2008, through<br>October 8, 2008<br><br>§1.702(a)(2)                          | 6 days charged to<br>PTO and <b>added</b><br>to PTA                   |

Total PTA = (Total added days) - (total subtracted days):

Total PTA = (435 + 256 + 6) – (3 + 86 + 22) = 586 days Correct Total PTA



UNITED STATES PATENT AND TRADEMARK OFFICE

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MAR 16 2009

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OFFICE OF PETITIONS

In re Application

Friedman, et al.

Application No. 10/780,295

Filed: February 17, 2004

Dkt. No.: 16454.00002 D2

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:  
: PATENT TERM ADJUSTMENT  
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This is a decision on the "APPLICATION FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.703(b)," filed January 7, 2009.

The application for patent term adjustment (PTA) under 37 CFR 1.705(b) is **HELD IN ABEYANCE**.

The Determination of Patent Term Adjustment under 35 U.S.C. 154(b), mailed October 8, 2008, indicated a patent term adjustment (PTA) to date of 330 days. The instant application for PTA was timely filed January 7, 2009 at the time of payment of the issue fee. Applicants argue that application is entitled to an additional adjustment of 256 days in accordance with 37 CFR 1.702(b).

Applicants contest the adjustment insofar as it relates to the Office's failure to issue the patent within three years of the filing date of the application pursuant to 37 CFR 1.703(b) in view of Wyeth v. Dudas, No. 07-1492 (D.D.C. September 30, 2008).

To the extent that this application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, a decision is being **held in abeyance** until after the actual patent date. Knowledge of the actual date the patent issues is ordinarily required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See, 37 CFR 1.703(b). It is noted that at the time of this decision, the patent has not issued.

Applicants are given **TWO (2) MONTHS** from the issue date of the patent to file a written request for reconsideration of the

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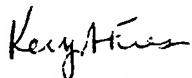
patent term adjustment for Office failure to issue the patent within 3 years. A copy of this decision should accompany the request. Applicants may seek such consideration without payment of an additional fee. However, as to all other bases for seeking reconsideration of the patent term adjustment indicated in the patent, all requirements of § 1.705(d) must be met. Requests for reconsideration on other bases must be timely filed and must include payment of the required fee.

With respect to the over 3 year calculation, rather than file the request for reconsideration of Patent Term Adjustment at the time of the mailing of the notice of allowance, applicants are advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term pursuant to 37 CFR 1.705(d). The USPTO notes that it does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent and accordingly, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent.

The required patent term adjustment application fee of \$200.00 has been charged to applicants' deposit account, as authorized.

The application file is being forwarded to the Office of Data Management for issuance of the patent. The patent term adjustment indicated on the patent (as shown on the Issue Notification mailed about three weeks prior to patent issuance) will include any additional adjustment accrued both for Office delay in issuing the patent more than four months after payment of the issue fee and satisfaction of all outstanding requirements, and for the Office taking in excess of three years to issue the patent (to the extent that the three-year period does not overlap with periods already accorded).

Telephone inquiries specific to this matter should be directed to Petitions Attorney Alesia M. Brown at (571) 272-3205.



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